NEGOTIATED RULEMAKING COMMITTEE ON THE SHARED RISK EXCEPTION

MINUTES[1]

January Meeting
January 21-22, 1998

The Negotiated Rulemaking Committee on the Shared Risk Exception held its seventh and final meeting on January 21-22, 1998 in Washington, D.C. The list of Committee Members and/or their alternates who attended is at **Attachment A**. At the end of the meeting, the Committee reached consensus and signed the Agreement at **Attachment B**.

FIRST DAY, JANUARY 21

The Committee convened at about 9:00 a.m. on January 21. A new draft proposal was circulated. The facilitators reviewed the proposed agenda, the meaning of consensus, and the status of the negotiations since the last meeting. The facilitators noted that a number of the Committee Members had identified concerns with the January 8 draft proposal distributed since the last meeting, but that these Members had not specifically identified them as concerns that would prevent them from coming to consensus ("drop dead" issues).

The facilitators then asked if any Committee Members had such "drop dead" issues--as distinguished from other things they wished to raise (for example, suggestions that might improve the proposal or were merely editorial). One Member indicated that he had to reserve consensus since he needed to consult with a few more of his constituents that he had not been able to reach. Other Members raised issues, which were recorded.

The facilitators asked whether the fact that these matters were identified as "drop dead" issues meant that the Committee Members raising the issues thought that the Committee would not be able to work them out and should therefore disband. These Committee Members then indicated that they did not want to discontinue negotiations.

After a review of the most recent changes to the proposal, Committee Members identified some additional issues, which were also recorded. The Federal agencies indicated that they would need to caucus before they could definitively respond to the issues raised. There was some discussion of the issues raised, followed by a break for lunch and to allow the Federal agencies to caucus. When the Committee recovened, the Federal agencies provided a further response to the issues raised, including some modifications they would accept. This was followed by further discussion. An opportunity was provided for oral statements from the public, but no one asked to address the

[1] These minutes were prepared by the facilitators for the convenience of the Committee Members and should not be construed to represent the official position of the Committee or of any Member on what transpired at the meeting.

Committee. The Committee adjourned shortly after 3:00 p.m. to allow Committee Members to consult with constituents.

Below, these minutes summarize the issues raised, some key points made during the discussions, and the results of the discussion.

Whether the preamble should clarify that a statutory change would not be necessary if it were later determined to expand the definitions of terms used in the statutory shared risk exception

One Committee Member suggested that there should be language in the preamble to clarify that a statutory change would not be necessary if it is determined in the future that, due to changes in payment methods, a provider (such as a long-term care provider) could be an "organization" for purposes of the second part ("prong 2") of the shared risk exception. Another Member suggested that future changes might also warrant modifications of the definitions of "risk sharing arrangement" (RSA) or "substantial financial risk" (SFR).

The IG representative responded that it is sufficiently clear that no statutory change would be required, particularly since the proposal includes as a preamble topic the fact that proposed changes to the safe harbor may be requested each year. No change was made to the proposal.

Whether proposed section (D) in prong 1 for contracts between "covered entities" and "first tier" individuals or entities would effectively remove from coverage certain arrangements that should be protected

One Committee Member said that arrangements which prong 1 appeared to cover at the first tier might not be covered because section (D) under "FIRST TIER" would require that the contract specify that the individual or entity cannot claim payment in any form from the Federal health care program. Specifically, this might exclude--

- arrangements between Federally qualified HMOs (FQHMOs) and their subcontractors, where the subcontractor is seeking Federal payment;
- arrangements between Medicaid managed care organizations and physicians who bill Medicare for "dual eligibles"; and
- arrangements where fee-for-service (FFS) payments are linked to the Medicare risk program, such as payments for hospice services.

With respect to FQHMOs, it was noted that the statutory language would appear to protect first tier arrangements (since an FQHMO is an "eligible organization"), so that the proposal would seem to be too narrow in that regard. To address this concern, the Committee modified the section (D) requirement.

With respect to Medicaid "dual eligibles," there was some discussion about the extent of this problem. A representative of States indicated that, in addition to Arizona, there are a few other States where there would be Medicare FFS billing for "dual eligibles" enrolled in Medicaid

managed care plans. Some health plan representatives indicated that States may pay lower capitation rates for "dual eligibles" and have "coordination of benefit" provisions that would require providers to bill Medicare for covered services as the primary payor. In addition, one representative noted that some Medicaid managed care organizations might also be receiving supplemental payments from the Maternal and Child Health program. He noted that existing safe harbors provide protection for these arrangements and suggested that language with similar effect be added to section (D) (such as, "except as approved by HCFA or the State health care program"). He indicated that it would be difficult for health plans to concur in a proposal that is more narrow than existing protections.

The Federal agencies agreed to further discussion of this (some of which occurred the following morning). Ultimately, some adjustments were made to the wording of section (D) and a preamble topic was added referring to the existing safe harbor for Medicad managed care and to an explicit request for comments on "coordination of benefits" provisions.

With respect to hospice and other services for which FFS payments may be made under Medicare risk contracts, the Federal agencies indicated that these are "carve outs," not covered by the risk contract. They indicated that the fact that a Medicare patient elects hospice care would mean only that the FFS payment to the hospice would not be protected, not that the whole relationship between the HMO and a first tier provider would not be protected.

Whether psychiatric hospitals should be excluded under the payment methodology standard for "substantial financial risk" (SFR)

Concerns were raised by hospital representatives about singling out psychiatric services and excluding them from the SFR standard. They noted that this exclusion was added for the first time in the December 18 version of the proposal.

The IG representative indicated that, while the language of the draft proposal was rather stark, the exclusion is not intended to be a general criticism of psychiatric services. He explained the following:

- The exclusion is limited to the payment methodology standard for diagnosis-related group (DRG) rates under prong 2. The IG had concerns about covering any DRGs under this standard since DRGs are episodic and therefore merely a bundled payment and not like capitation where the provider takes full responsibility for care of the patient over a period of time.
- The Federal agencies are willing to cover DRG rates for non-psychiatric inpatient hospital services on the theory that such hospitalization is undesirable and this counteracts any incentive to overutilize. They do not think they have the same assurance with respect to inpatient psychiatric services, where there is less objectivity and less ability to determine in advance the need for the services.
- They view this as a patient protection issue since there have been instances of kickbacks

where patients were placed in psychiatric hospitals, retained until coverage was exhausted, and then put out on the street.

There was some discussion about the extent to which psychiatric services are paid under DRGs and the reason why DRGs were not applied across the board to psychiatric services. It was noted that if DRGs are extended more generally to inpatient psychiatric hospital services, psychiatric hospitals could request that the safe harbor be modified.

Ultimately, a wording change was made to clarify that the exclusion applies only to the provision on what DRGs are protected under the payment methodology standard, and a preamble topic was added to explain the reasons why.

Whether the preamble should explain that a "bright line" approach is being used, but that large numbers of legitimate transactions outside of the rule ("safe harbor") will be legal and that providers do not need to torture their transactions to fit within the rule

One Committee Member raising this issue stated the opinion that, from the perspective of physicians, the safe harbor is narrow and, therefore, the preamble would be very important. He indicated there are large numbers of categories of transactions excluded from prong 2, such as physician-owned HMOs, and no one wants to imply that all those transactions would be illegal. He explained why he thought it would be insufficient to include in the preamble traditional language indicating that the fact that a transaction does not fall within a safe harbor does not mean that it is illegal. He indicated a concern that the rule will drive transactions in the marketplace unless this concept is fully understood.

The IG representative indicated that the Federal agencies were willing to expound on the issue more than they have in the past. He indicated that the preamble would explain that people should not draw conclusions with respect to an arrangement that is outside the safe harbor. He disagreed, however, that the proposal as a whole is a narrow approach. He expressed his opinion that, taken as a whole, the proposal is a significant expansion of safe harbor protection. He indicated that, while the Federal agencies are willing to describe some arrangements that cause them concern, they are wary of implying that any arrangement not specifically identified as abusive is legal. He agreed, generally, however, that the safe harbor should not drive the market.

A few new preamble topics were added in response to this discussion.

Whether transactions similar to those described in a new management advisory report would be included in the safe harbor

A new "Management Advisory Report" (similar to a "Special Fraud Alert") addresses possible kickback arrangements where a hospital either pays below market value or no money for Medicare Part A services performed by a hospital-based physician or extracts something else of value from the physician, in exchange for a franchise for the physician to bill Medicare Part B services.

In response to a question about whether such transactions would be included in the safe harbor, IG staff indicated that they did not see how these transactions would be part of a "risk sharing arrangement" (RSA). One Committee Member clarified that the questions are: 1) whether, where a hospital-based physician is being asked to make a contribution in return for referral of patients, the fact that patients are referred through an RSA immunizes the transaction; and 2) if not (which is the expected answer), whether this is consistent with the Federal agencies' concerns about physician owners getting a return on their investment that is outside the RSA and is in fact a reward.

The IG staff response was that the fact that there is a protected RSA between a hospital (or a PHO) and an HMO would not somehow make forced inducements between the hospital and hospital-based physicians part of the RSA. They explained that an investment interest of a physician-owner would be a transaction not similarly viewed as independent of the RSA because the return on investment could effectively defeat the SFR in the RSA.

Whether Federally-qualified health centers (FQHCs) would be protected at the "first tier" under prong 2 and whether FQHCs would be protected "downstream" under prong 1

One Committee Member asked how the prong 2 requirements for an "organization" under section (D) would apply to the following: a managed care organization, such as an HMO, that is owned by FQHCs contracts with a State to provide Medicaid services (including mental health services on a FFS basis) and subcontracts with individual FQHCs, which likely serve a large number of Medicare beneficiaries.

Other Committee Members pointed out that since the FQHCs would be owners of the organization, prong 2 would not apply, regardless of whether the section (D) requirements were met. It was noted, however, that Medicaid arrangements might fit under prong 1.

The question was later asked whether downstream arrangements involving FQHCs would be excluded from protection under prong 1 if the FQHCs are <u>not</u> receiving supplemental Federal payments (which was the reason for the exclusion). As a result of this question, the second bullet in the proposal for "downstream" individuals or entities in prong 1 was modified to read: "No downstream protection for Federally qualified health centers receiving supplemental payments, cost-based HMOs, or Federally qualified HMOs."

What activities may occur after consensus has been reached?

The facilitators noted that a change had been made in Article 7 of the draft Agreement, based on the Committee's discussion at the December meeting, to clarify that, if the preamble explicitly requests comment, Committee Members will be free to comment. The Committee then identified one area under "Preamble Topics" currently noting that comments would be requested, related to the percentages in the numeric standard for SFR. The Committee also listed several other specific areas for consideration of this treatment. One Committee Member suggested that comment be requested on all of prong 2, since Members would be struggling to explain prong 2 to their constituents.

The Federal agencies indicated that they would discuss whether to request comments on the specific areas raised, but would be concerned about inviting more comments generally. They indicated that the negotiated rulemaking process should substitute for notice and comment by the Members, and that the benefit to the Federal agencies in reducing comments between the interim and final rules would be lost if general comments were permitted.

It was noted that the groundrules provide for the Committee to reconvene if necessary in order to address comments, and that any changes as the result of comments would need to be explained.

The Committee then discussed what is meant by the agreement not to take action to inhibit adoption as a final rule of the interim final rule (or, possibly, proposed rule for some parts of the proposal)--to the extent it has the same substance and effect as a Committee Statement. Specifically, one Committee Member asked whether the agreement would prohibit lobbying activity to change the statute. Several Committee Members indicated that they viewed the prohibition as being related to the regulation under existing law, and not to future legislative changes. No one expressed disagreement with this view.

Generally, there was a recognition that Committee Members could explain the negotiation process and its result to their constituents. This could include describing what were the difficult areas, and indicating that the result as a whole is one that the Committee could live with.

On the other hand, Committee Members expressed concern that other Members not act in bad faith by trying to "gin up" negative comments, either from their constituents or in the press. One Member noted that the nature of any public comments should be such that they do not undermine what the Committee has said it can live with.

Which numeric standard (institutional or non-institutional) for SFR would apply where hospital and physician money is pooled?

Several Committee Members asked whether the institutional (10%) numeric standard or the non-institutional (20%) numeric standard for SFR would apply if hospitals and physicians had pooled their money, such as by forming a joint-venture physician hospital organization (PHO). The response was that an upstream arrangement of the PHO with a managed care organization would be subject to the 20% standard since a PHO is not an institution. It was noted, however, that the

preamble would request comment on whether additional individuals or entities should be considered for institutional treatment.

Whether the provision under RSA regarding arrangements that "set payment rates based on payor source or billing method" is limited to prong 2 and how it relates to overutilization

One Committee Member asked about the second sentence in the first bullet under "RISK SHARING ARRANGEMENT," which states: "Arrangements which set payment rates based on payor source or billing method are not protected." He asked whether it was limited to prong 2 and was told that that was correct.

He also stated that there are many arrangements where there are different rates for Medicare, commercial, and Medicaid and suggested that the sentence be deleted as unnecessary.

An IG staff person explained that the key idea from their point of view is that expressed in the following sentence: " . . . payment must be the same for identical items or services provided to persons with similar health status." This provision, he said, ensures that, even if Medicare services are paid on an FFS basis, Medicare beneficiaries will be treated the same as other enrollees in the health plan. The problem, he said, with what was described as a common practice is that grouping the patients by payor source could mean that over-65 Medicare beneficiaries would not be treated the same as any over-65 employees in the commercial plan, even if their health status is the same. The Federal agencies are nervous that the FFS population could be "gamed" and therefore need the assurance that this population is being treated the same as other enrollees and is subject to the same utilization targets.

One Committee Members noted that the problem raised is a practical issue, since the provision would require that there be appropriate risk adjusters for different populations. Another noted that the greater hurdle in prong 2 will be getting the organization to do the billing, and that, if the organization is willing to bill, downstream arrangements can be structured to meet the requirement.

No change was made as a result of this discussion.

Whether an FQHC should qualify as an "institution" for purposes of the numeric standard for SFR

The first response to this question was that FQHCs would not qualify as an "institution" for purposes of applying the 10% numeric standard for SFR under prong 2. As a result of later discussion, however, the preamble topic on the appropriateness of payment percentages was modified to indicate that the preamble will inquire about whether FQHCs should be considered for institutional treatment.

Whether the change to the lead-in language to prong 1, making an explicit statement about

downstream entities, covers more than subcontractors

In response to this question, it was clarified that suppliers were covered.

What is full capitation?

Although this issue was not raised initially, it ultimately led to considerable discussion. The primary concern raised was whether an arrangement in which there is a capitation payment would be considered full capitation for purposes of the payment methodology standard for SFR, even if provider liability was limited by stop-loss insurance.

The Federal agencies indicated that, since it was their understanding that it would be financially prohibitive to obtain commercial stop-loss insurance that would reduce the risk substantially, they would be willing to indicate in the preamble that puchase of commercial stop-loss in an arms' length transaction would be permissible (although aggregate stop-loss from an upstream provider would be analyzed under the numeric standard).

The representative of State insurance regulators indicated, however, that she would have difficulty selling to her constituents any provision referring to stop-loss since there is current litigation about when stop-loss should be subject to State regulation as insurance. She noted that this had just been raised as an issue and not fully thought out.

Ultimately, a preamble topic was added to request comment on "the extent to which full capitation is implicated by the purchase of commercial stop loss or contractual provisions regarding the limitation of liability."

One Committee Member also noted a need for clarification that a payment could qualify as "full capitation" even if it is not a "global fee" covering the full range of services. She was told that this would be clarified in the preamble.

SECOND DAY, JANUARY 22

The Committee reconvened at about 10:40 a.m. on January 22. The Committee reviewed a Committee Statement (basically, the proposal presented the previous day as modified based on discussions the previous day or that morning). The facilitators asked whether any Committee Members had any comments. One asked whether the "Preamble Topics" pages were part of the Committee Statement and was told that they were.

The facilitators then asked whether there was any Committee Member who could not live with the Committee Statement. No one responded. Committee Members then signed the Agreement (which incorporates the Committee Statement by reference).

ATTACHMENT A - LIST OF PARTICIPANTS

Committee Members present for part or all of the meeting:

Candace Schaller, AAHP
Cheryl Matheis, AARP
Elise Smith, AHCA
Mary R. Grealy, AHA
Edward B. Hirshfeld, AMA
Brent Miller, AMGA
Susan E. Nestor, BCBSA
Charles P. Sabatino, CCQHC
Missy Shaffer, CCC
Laura Thevenot, FAHS
Kathleen Fyffe, HIAA
Eddie Allen, HIMA
Stephen M. Spahr, NAMFCU
Lee Partridge, NASMD
S. Lawrence Kocot, NACDS
Karen A. Morrissette, DOJ
Don Brain, IIAA/NAHU/NALU
D. McCarty Thornton, OIG/HHS

Alternates substituting for Committee Members:

Marjorie Powell, PhRMA
Mary Beth Senkewicz, NAIC
Roger Schwartz, NACHC
Linda Rouse, NRHA
Brent Phillips, TIPAAA

Alternates attending and/or substituting for Committee Member for part of the meeting:

Mark Joffe, AAHP; Howard Sollins, AHCA; Kathy Nino, AMA; Mary L. Kuffner, AMGA; Bob Wallace, DOJ; Thomas Bruderle, Nancy Trenti, IIAA/NAHU/NALU; Douglas Guerdat, BCBSA; Mark H. Gallant, NACDS; Barbara Zelner, NAMFCU; Kevin McAnaney, OIG/HHS; Thomas Scully, FAHS; Jennifer Goodman, NASMD; Marcie Zakheim, NACHC

ATTACHMENT B

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
NEGOTIATED RULEMAKING COMMITTEE ON
THE SHARED RISK EXCEPTION

The Negotiated Rulemaking Committee on the Shared Risk Exception (Committee) considered issues related to establishing standards for section 216 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Section 216 excepts certain remuneration from Federal healthcare anti-kickback provisions at section 1128B of the Social Security Act.

The parties whose signatures appear on this document agree that--

1. The individual signing this agreement is authorized to commit the party to the terms of the agreement.

2. The party concurs in the attached written statement, dated January 22, 1998 and attached as Exhibit 1 (Committee Statement), when considered as a whole.

3. The Department of Health and Human Services (HHS), through the Office of the Inspector General (OIG), agrees that it will, to the maximum extent possible consistent with the Department's legal obligations, draft preamble language and an interim final rule, subject to comment, consistent with those parts of the Committee Statement that address standards for section 216 of HIPAA.

4. HHS, through the OIG, agrees that it will consider issuing a rule (which may either be a notice of proposed rulemaking or an interim final rule) on the matters designated as “HHS Regulatory Authority” in the Committee Statement. A rule on these matters is outside the scope of Section 216 of HIPAA, and would be promulgated under the HHS authority (section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987) to issue rules constituting “safe harbors” under the anti-kickback statute.

5. If HHS determines to exercise its discretionary authority to publish the rule described in Article 4 above, HHS will publish at the same time the interim final rule described in Article 3, the rule described in Article 4, and the related preamble language.

6. Each party agrees not to file negative comments on the interim final rule described in Article 3, the rule described in Article 4, or the preamble to the extent that, considered as a whole, they have the same substance and effect as

the Committee Statement. If a party determines that it has a right to submit negative comments because what is published does not have the same substance and effect as the Committee Statement, the Committee Member will notify other Committee Members and state the basis for this determination.

7. Each party may comment on any matter in the interim final rule described in Article 3, the rule described in Article 4, or the preamble that either is not addressed in the Committee Statement or is a matter on which the preamble explicitly requests comment from the public.

8. After the close of the comment period on the interim final rule described in Article 3 and the rule described in Article 4, the facilitator will consult with the Committee to determine whether the Committee will reconvene to consider comments before the final rule is circulated for review and approval within the appropriate Federal agencies.

9. Except for the appropriate Federal agencies, each party that signs the agreement agrees not to take any action to inhibit the adoption as a final rule of either the interim final rule described in Article 3 or the rule described in Article 4 to the extent that the final rule and its preamble have the same substance and effect as the Committee Statement. In the preamble, the appropriate Federal agencies will note, and explain the rationale for, any difference between the final rule and the Committee Statement.

10. No party is bound under Article 9 with respect to any matter not addressed in the Committee Statement.

11. No party is bound by this Agreement if the Secretary does not act in accordance with Article 5.

_____	_____
Representative	***Representative***
American Association of Health Plans	***BlueCross BlueShield Association***
_____	_____
Representative	***Representative***
American Association of Retired Persons	***Consumer Coalition for Quality Health Care***

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Representative
American Health Care Association

_____
Representative
American Hospital Association

_____
Representative
American Medical Association

_____
Representative
American Medical Group Association

_____
Representative
Independent Insurance Agents of America
National Association of Health Underwriters
National Association of Life Underwriters

_____
Representative
National Association of Chain Drug Stores

_____
Representative
National Association of Community Health Centers

_____
Representative
National Association of Insurance Commissioners

_____
Representative
National Association of Medicaid Fraud Control Units

_____
Representative
National Association of State Medicaid Directors

_____
Representative
Coordinated Care Coalition

_____
Representative
Federation of American Health Systems

_____
Representative
Health Industry Manufacturers Association

_____
Representative
Health Insurance Association of America

_____
Representative
National Rural Health Association

_____
Representative
Pharmaceutical Research and Manufacturers of America

_____
Representative
The IPA Association of America

_____
Representative
Department of Justice

_____
Representative
Department of Health and Human Services

NEGOTIATED RULEMAKING COMMITTEE
on the SHARED RISK EXCEPTION

Committee Statement

January 22, 1998

The Negotiated Rulemaking Committee on the Shared Risk Exception has concurred in the following recommendations, considered as a whole, on the content of regulations (and related preamble topics) establishing standards for section 216 of the Health Insurance Portability and Accountability Act of 1996 and addressing related issues.

SAFE HARBORS FOR MANAGED CARE PLANS AND ASSOCIATED INDIVIDUALS OR ENTITIES

I.
Managed Care Organizations under Federal Health Care Programs

(n) ***Price reductions offered to covered entities.*** "Remuneration" under the anti-kickback statute does not include any remuneration between a "covered entity" (see below) and an individual or entity or between an upstream individual or entity and its subcontractors, subject to the standards below.

COVERED ENTITIES

- "Eligible organization under 1876"
    - risk-based HMOs and competitive medical plans with Medicare contracts
    - for arrangements with first tier individuals or entities only, cost-based HMOs and competitive medical plans with Medicare contracts
    - for arrangements with first tier individuals or entities only, federally qualified HMOs (without regard to Medicare contracts) for their capitated enrollees, including where a Federal health care program is a secondary payor.
- Any Medicare Part C health plan which receives a capitated payment from

Medicare and which must have its total Medicare beneficiary cost sharing approved by HCFA under section 1854 of the Social Security Act. Medicare+Choice fee-for-service panels and medical savings account plans are specifically excluded. **(HHS Regulatory Authority)**[2]

- Medicaid managed care organizations as defined in section 1903(m)(1)(A) (except for fee-for-service plans or medical savings accounts) which provide or arrange for services for Medicaid enrollees under a contract pursuant to section 1903(m). This includes section 1915(b) waivers, section 1115 waivers that do not waive 1903(m) provisions, and Medicaid managed care organizations under section 1932. **(HHS Regulatory Authority)**

- With respect to 1115 waivers which waive section 1903(m) provisions, those health plans which have risk-based contracts with a state agency and provide or arrange for services for Medicaid enrollees and which meet all of the requirements of section 1903(m) except for section 1903(m)(2)(a)(vi) as waived by the Secretary will be covered.[3] **(HHS Regulatory Authority)**

- PACE (except for for-profit demonstrations under section 4801(h) and 4802(h)). **(HHS Regulatory Authority)**

- TriCare **(HHS Regulatory Authority)**

"FIRST TIER" Individuals or Entities

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[2] "HHS Regulatory Authority" issues are outside the scope of 216 of HIPAA. Rulemaking on such issues is governed by the APA notice and comment procedures, not the negotiated rulemaking procedures.

[3] The language for the safe harbor will also provide coverage for arrangements with the Arizona Health Care Cost Containment System.

- Where the individual or entity provides directly or arranges for items or services to be provided to members, the covered entity and the individual or entity providing or arranging for the items or services must have an agreement which:

    (A) is set out in writing and signed by both parties;
    (B) specifies the items and services covered by the agreement;
    (C) is for a period of at least one year; and
    (D) specifies that the individual or entity cannot claim payment in any form from a Federal health care program for items and services covered under the agreement, except as to Federally qualified HMOs or Medicare 1876 cost contractors where the Federally qualified HMO, Medicare 1876 cost contractor or its first tier provider is billing a Federal health care program, in which case, the billing arrangement must be set forth in the agreement.

- Except as provided in (D) above, covered entities may not claim payment in any form from a Federal health care program for items or services, other than the contractual amounts sets forth in the covered entity's agreement with the Federal health care program.

- Arrangements between a covered entity and a Federally qualified health center are covered.

"DOWNSTREAM" INDIVIDUALS OR ENTITIES **(HHS Regulatory Authority)**

- An upstream and a downstream individual or entity must have a contract which:

    (A) is set out in writing and signed by parties to the contract;
    (B) specifies the items and services covered by the agreement;
    (C) is for a period of at least one year; and
    (D) specifies that the individual or entity cannot claim payment in any form from a Federal health care program.

- No downstream protection for Federally qualified health centers receiving supplemental payments, cost-based HMOs, or Federally qualified HMOs.

TRADING BUSINESS

- In establishing the terms of the arrangement, neither the upstream nor downstream

individual or entity gives or receives remuneration in return for or to induce the other party to provide or accept business (other than that covered by the arrangement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis. In addition, the arrangement is not protected when it shifts the burden of such an arrangement to the extent that increased payments are claimed from a Federal health care program. This provision does not prevent parties from establishing different payment rates for different products.

- The preamble would also make clear that an arrangement which fits within a safe harbor is only protected from prosecution under the Federal anti-kickback statute. The safe harbors do not provide protection from any other Federal or state laws.

DEFINITIONS

- For purposes of this paragraph, the definitions of the certain terms are set forth as follows:
  (i) **items or services** only includes health items, devices, supplies, or services or those reasonably related to the provision of health care items, devices, supplies or services provided to enrollees, including, but not limited to, non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance. Marketing services and services provided prior to enrollment are not covered.

II.

Managed Care Risk-Sharing Arrangements Where Federal Program Pays Fee-For-Service[4]

(o) Managed care organization risk-sharing arrangements. "Remuneration" under the anti-kickback statute does not include any remuneration between an organization and an individual or entity or between an upstream individual or entity and its subcontractors, where there is a risk sharing arrangement ("RSA") that puts the individual or entity at substantial financial risk ("SFR") for the cost or utilization of items or services, if the requirements below are met.

"ORGANIZATION"

- The organization is a health plan as defined in 42 C.F.R. 1001.952(l)(2) and which provides a comprehensive range of health services. In addition, each written agreement of the organization which qualifies for protection must provide for:

    (A) reasonable utilization goals to avoid inappropriate utilization;
    (B) an operational utilization review program;
    (C) a quality assurance program that promotes the coordination of care, protects against underutilization, and specifies patient goals, including measurable outcomes where appropriate;
    (D) grievance and hearing procedures;
    (E) protection for members from incurring financial liability (except as to copayments and deductibles);
    (F) no treatment for Federal health care program beneficiaries that is any different than other enrollees due to their status as Federal health care program beneficiaries; and
    (G) either

        (i) no more than 10 % Medicare beneficiaries as enrollees where a Federal health care program is primary

        or

[4] Prong 2 also includes Medicaid 1115 waivers that do not fit under prong 1.

(ii)(a) at least 50% non-Medicare beneficiaries as enrollees where a Federal health care program is not primary

and

(b) receipt of payments for premiums under the RSA on a periodic basis that does not take into account the dates services are provided, the frequency of services, or the extent or kind of services provided.

- The organization's written agreements which have protection do not lose protection, if the organization has additional non-protected agreements.

"RISK SHARING ARRANGEMENT"

- In order for an arrangement to be protected, items or services covered by a Federal health care program must be included in the RSA. Arrangements which set payment rates based on payor source or billing method are not protected. In other words, payment must be the same for identical items or services provided to persons with similar health status. In addition, the organization[5] must bill the Federal health care program except as provided below; arrangements where the individual or entity bills Federal health care programs directly, on a fee-for-service or cost basis would not be protected. Nothing shall be construed to disallow appropriate plan payment adjustments to individuals or entities which are related to utilization patterns and/or costs of providing items or services to the relevant population.

  Other types of arrangements which qualify as a RSA:

  - An arrangement is deemed to be a RSA if the organization receives a fixed, periodic payment for its non-Federal health care program fee-for-service enrollees, and includes Federal health care program beneficiaries in its downstream RSAs.

  - Inpatient services provided by hospitals will be deemed to be part of the RSA if the hospital is reimbursed by the Federal health care program directly on a DRG basis. Organizations must reimburse hospitals for inpatient hospital services provided to non-Medicare enrollees on a DRG basis, although payment amounts may be different.

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[5] In the case of a self-funded employer plan that contracts with an organization to provide administrative services (i.e., a TPA or an ASO) the self-funded employer plan must bill.

- Part B services will be deemed included in the RSA if the Part B supplier receives a capitated or other risk payment from the organization (or the upstream individual or entity) and reassigns its rights to Federal health care program fee-for-service payments to the organization.

- The safe harbor does not protect any arrangement between a first tier individual or

entity and an organization, where the individual or entity has an investment interest in the organization, unless the investment interest meets the criteria of 42 C.F.R. 1001.952(a)(1).

"SUBSTANTIAL FINANCIAL RISK" (SFR)

- RSAs must meet one of the following standards for SFR:

(A) **Payment Methodology Standard** -- an individual or entity is at SFR if payments to the individual or entity under the RSA are made under any one or more of the following:

(i) full capitation (to be defined);
(ii) percentage of premium; or
(iii) inpatient Federal health care program DRGs, except those for psychiatric services.

under these arrangements, the reimbursement must be reasonable given the historical utilization patterns and costs for the same or comparable population in similar managed care arrangements.

- any payments outside of the risk sharing arrangement (including outlier payments and special procedure payments on a fee-for-service basis, such as transplants) are not protected under this safe harbor.

(B) **Numeric Standard** -- an individual or entity is at SFR if:

(i) the target payment

(a) for non-institutional individuals or entities is at least 20% greater than the minimum payment or

(b) for institutional individuals or entities (hospitals and nursing homes) is at least 10% greater than the minimum payment.[6]

[6] In either case, the arrangement must ensure that the amount at risk, i.e., the bonus/withhold, is earned by an individual or entity in direct relation to the ratio of the actual to the target utilization. The minimum payment may not be set artificially low.

(ii) Definitions

(a) **target payment** is the fair market value payment established through arms length negotiations that will be earned by an individual or entity and that:

1. is dependent on the individual or entity's meeting a utilization target or range of utilization targets, which are set consistent with historical utilization rates for the same or comparable populations in similar managed care arrangements, whether based on his/her own, a group's or the plan's utilization (or a combination thereof); and

2. does not include any bonus or fees which the individual or entity may earn from achieving utilization below the utilization target level or range.

(b) **minimum payment** is the guaranteed amount that an individual or entity is entitled to receive under the contract.

(c) the target payment and minimum payment both include any bonus for performance (examples: timely submission of paperwork, continuing medical education, meeting attendance) at a level achieved by 75 percent of participating individuals or entities who are paid a performance bonus based on the same bonus structure under the arrangement.

(C) **Physician Incentive Plan Standard** a physician is at SFR if:

(i) the upstream individual or entity has placed the physician at substantial financial risk for referral services in an amount that exceeds the substantial financial risk threshold under the Department's physician incentive plan regulations and the arrangement is in compliance with the stop-loss and beneficiary survey requirements of those regulations.

(ii) notwithstanding the foregoing, an individual or entity will not be at substantial financial risk, for purposes of this standard, if the patient panel size is 25,000 covered lives or greater.

"OBLIGATED TO PROVIDE"

- To fall within the exception, the individual or entity's SFR must be for the cost or utilization of services, which the individual or entity is "obligated to provide." This includes:

  (A) services provided directly by the individual or entity and its employees;
  (B) services for which the individual or entity is financially responsible but which are provided by subcontractors;
  (C) services for which the individual or entity makes referrals or arrangements; and **(HHS Regulatory Authority)**
  (D) services for which individuals or entities receive incentives based on his or her own, group, or plan's performance. **(HHS Regulatory Authority)**

DOWNSTREAM INDIVIDUALS OR ENTITIES

- Exception includes written agreements between upstream and downstream individuals or entities. However, in order to prevent fee-for-service or cost-based kickbacks disguised as risk sharing arrangements by "non-SFR individuals or entities," downstream individuals or entities are only protected if they are paid on an SFR basis by another individual or entity who is also paid on an SFR basis. In other words, contracts involving an individual or entity which is <u>not</u> paid on an SFR basis are <u>not</u> protected for <u>any</u> party. For example:

  (1) HMO (capitated)
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  | \
  | / arrangement between levels 1 and 2 protected
  |/
  (2) PHO (percentage of premium -- physician and hospital services)
  |\
  | \
  | / arrangement between levels 2 and 3 not protected
  |/
  (3) IPA (fee for service) ("Non-SFR Individual or entity")
  |\
  | \
  | / arrangement between levels 3 and 4 not protected
  |/
  (4) Physician group (capitated)

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| \
| / arrangement between levels 4 and 5 protected
|/

(5) Physician (capitated)

DEFINITIONS

- **items or services** only includes health items, devices, supplies, or services or those reasonably related to the provision of health care items, devices, supplies or services provided to enrollees, including, but not limited to, non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance. Marketing services and services provided prior to enrollment are not covered.

- **the written agreement** between the organization and an individual or entity, and downstream contracts between individuals or entities must:

  (A) set out in writing and signed by the parties;
  (B) specify the items and services covered by the agreement;
  (C) specify the intervals at which distributions will be paid;
  (D) specify the formula for calculating incentives and penalties;
  (E) set out that the arrangement is for a period of at least one year;
  (F) specify the methodology for determining compensation which is commercially reasonable and which is set in advance in arms-length negotiations; and
  (G) require participation in a quality assurance program that promotes the coordination of care, protects against underutilization, and specifies patient goals, including measurable outcomes where appropriate.

TRADING BUSINESS

- In establishing the terms of the arrangement, neither the upstream nor downstream individual or entity gives or receives remuneration in return for or to induce the other party to provide or accept business (other than that covered by the arrangement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis. In addition, the arrangement is not protected when it shifts the burden of such an arrangement to the extent that increased payments are claimed from a Federal health care program. This provision does not prevent parties from establishing different payment rates for different products.

- For purposes of the arrangement between the payor and the organization, the periodic payments for the non-Federal health care program primary enrollee to the organization cannot vary according to the number of Federal health care program fee-for-service beneficiaries being serviced under the agreement or under other

agreements.

- The preamble would also make clear that an arrangement which fits within a safe harbor is only protected from prosecution under the Federal anti-kickback statute. The safe harbors do not provide protection from any other Federal or state laws.

PREAMBLE TOPICS

GENERAL

- Safe harbors set forth practices that would be immune from sanction under section 1128(b) of the SSA.

- To be emphasized: The fact that an arrangement does not comply with a safe harbor does not mean that an arrangement is illegal. It is not correct to assume that arrangements outside of a safe harbor are suspect due to that fact alone. Safe harbor regulations do not expand the scope of activities that the anti-kickback statute prohibits. It means only that the arrangement does not have guaranteed protection.

- Numerous managed care arrangements that exist in the market place today neither fall within this safe harbor, nor are they illegal.

- Simply because an arrangement complies with a safe harbor does not immunize or otherwise legitimize such an arrangement from other Federal and state laws. For example, the regulations will not pre-empt the need for arrangement to meet applicable state licensure laws, antitrust laws, and other Federal and state laws.

- An arrangement that potentially falls under more than one safe harbor need only meet all of the requirements of one safe harbor, not both.

- For specific arrangements that are not covered by this safe harbor (such as certain HCFA demonstration projects not covered by prong I), individual requesters are encouraged to submit requests for advisory opinions.

- General summary of areas where there was major discussion over issues and what some of those issues were, followed by a statement about reaching consensus on the whole proposal. Explain that we would consider amending the regulation at a later point in time through our annual solicitation for new safe harbors.

- Explain “consensus”.

SCOPE OF THE SAFE HARBOR

- If a contract covers items or services that are part of both a protected covered arrangement under this safe harbor (either prong I or prong II) and extend beyond that arrangement, only the items or services that are part of the protected

arrangement are covered.

- Remuneration in the form of profit distributions from investment interests are not protected by this safe harbor. Individuals or entities seeking safe harbor protection would also need to meet all of the requirements of another safe harbor, such as the safe harbor for investment interests in small entities. This safe harbor only protects the remuneration paid for the provision of items or services between an "organization" and an individual or entity or between downstream individuals or entities.

FIRST TIER INDIVIDUALS OR ENTITIES

- The existing safe harbors afford substantial protection for Medicaid managed care plans under 42 C.F.R. 1001.952(m). We will solicit comments for purposes of this safe harbor, concerning how situations where coordination of benefits laws require either a Medicaid managed care plan or an individual or entity under such a plan, to bill another Federal health care program on a fee-for-service basis for the Medicaid eligible. One suggestion to resolve this issue would be to grant safe harbor protection in instances where (1) the Medicaid plan bills the Federal health care program, (2) the individual or entity is paid by the Medicaid plan in the same amount and in the same way as for those enrollees who are not subject to the coordination of benefits, and (3) neither the plan nor the individual or entity otherwise shifts the burden of such an arrangement to the extent that increased payments are claimed from a Federal health care program.

DEFINITION OF ORGANIZATION

- The prong II requirement that 50% of the enrollees of an organization be non-Medicare is for the top tier only and does not extend "downstream".

- Discussion of self-funded ERISA plans and TPAs.

- We recognize that measurable outcomes do not exist for many services provided by individuals or entities, so the expectation of including measurable outcomes is intended to apply only where such measures make sense from the clinical perspective of the particular individual or entity. One type of measurable outcome may include patient satisfaction measures.

ITEMS AND SERVICES

- The interim final rule does not cover "items or services" provided to enrollees prior

to their enrollment. Also, it does not cover "marketing" services. However, simply because such services are not included in the safe harbor does not mean that they are *per se* illegal.

- Nurse call-in lines for current enrollees of an organization are not marketing under this regulation. Marketing does include items such as "value-added services."

- The definition of items or services includes services provided to individuals or entities that are reasonably related to the services being delivered to enrollees (i.e., disease management).

RISK SHARING ARRANGEMENTS

- Fee-for-service or case rate payments for specific items and services, such as transplants, do not disqualify an arrangement that otherwise shares risk, from being a RSA. However, the payments made outside of the RSA are not protected. Such arrangements may be scrutinized for inappropriate swapping.

SUBSTANTIAL FINANCIAL RISK

- The definition of SFR in these regulations applies only to the anti-kickback statute. It has no applicability to any other laws, including the anti-trust laws.

- We will request the submission of data on the appropriateness of different target payment percentages for institutional and non-institutional individuals or entities during the comment period. Specifically, we will inquire whether additional individuals or entities, such as pharmacy providers, manufacturers, or Federally qualified health centers, should be considered for institutional treatment. In addition, as more research and data become available, the target payment percentages may be revised.

- The numeric definition of SFR for institutional and non-institutional individuals or entities is for purposes of this regulation only and is not meant to be used for other purposes.

- It is not necessary in year one of an arrangement to include the performance bonus for 75% of the participating individual or entities in the SFR calculation.

- Explain reasons for excluding ownership of the organization by first tier providers. The mere existence of this ownership relationship is not a ground for concern.

- The percentages in the numeric standard represent the threshold at which the government has confidence that the risk of program or patient fraud or abuse is minimal.

- We will request comments on the extent to which full capitation is implicated by the purchase of commercial stop loss or contractual provisions regarding the limitation of financial liability.

- Under the DRG Payment Methodology Standard, DRGs for psychiatric services are not included due to past enforcement problems. This policy is necessary for protection of patients seeking these services.

- Hybrid arrangements such as combinations of capitated payments with bonuses and withholds will by analyzed under the numeric standard.

SWAPPING

- The language "shifts the burden" set out in this swapping provision, as well as prior safe harbors, means that the financial burden of an arrangement can not be shifted to a Federal program. For example, an individual or entity cannot increase the number of claims submitted or increase the charges or costs for services in order to subsidize the costs of other less profitable lines of business.

- In terms of the swapping requirements, there is no difference whether multiple lines of business are part of one arrangement or several arrangements.